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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/027,913	12/20/2001	Gojendra Nath Bordoloi	3108/OK142	9950
7590 01/30/2004		EXAMINER		
DARBY & DARBY P.C.			MARX, IRENE	
805 Third Avenue New York, NY 10022			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application N .	Applicant(s)				
, 	10/027,913	BORDOLOI ET AL.				
Office Action Summary	Examiner	Art Unit				
	Irene Marx	1651				
Th MAILING DATE of this communication appears on the cover sheet with the correspondence address						
P riod for R ply						
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statute - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be tin within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).				
Status	4 0000					
1) Responsive to communication(s) filed on <u>07 N</u>						
,	action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims		•				
4)⊠ Claim(s) <u>1-12</u> is/are pending in the application.						
4a) Of the above claim(s) 3-12 is/are withdraw	4a) Of the above claim(s) 3-12 is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1 and 2</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/o	r election requirement.					
Application Papers						
9) The specification is objected to by the Examine						
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
•	kaminer. Note the attached Office	ACTION OF TORIN 1 TO TOE.				
Priority under 35 U.S.C. §§ 119 and 120	051100 6440/	-) (d) or (f)				
12) △ Acknowledgment is made of a claim for foreign a) ☐ All b) ☐ Some * c) ☒ None of: 1. ☐ Certified copies of the priority document 2. ☐ Certified copies of the priority document 3. ☒ Copies of the certified copies of the priority document application from the International Burea * See the attached detailed Office action for a list 13) ☐ Acknowledgment is made of a claim for domest since a specific reference was included in the first 37 CFR 1.78. a) ☐ The translation of the foreign language process. 14) ☐ Acknowledgment is made of a claim for domest reference was included in the first sentence of the second content of the foreign language process.	ts have been received. Its have been received in Application of the certified copies not received in Application of the certified copies not received priority under 35 U.S.C. § 1190 of the sentence of the specification of the certified copies not received by the certification of the specification of th	ion No ed-in-this National-Stage ed. e) (to a provisional application) r in an Application Data Sheet. ceived. 0 and/or 121 since a specific				
Attachment(s)	-	(DTO 440) D				
 Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 	5) Notice of Informal	y (PTO-413) Paper No(s) · Patent Application (PTO-152)				

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The application should be reviewed for errors. Error occurs, for example, in the spelling of "wherien" in claim 1.

Applicant's election with traverse of Group I on 11/7/03 is acknowledged. The traversal is on the ground(s) that because there is lack of serious burden.

However this is not found persuasive because for purposes of the initial restriction requirement a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 808.02. That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re*

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Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is redundant in the recitation of "novel". The term "and" appears to be missing between "antifungal" and "antibacterial"

Claim 1 is incomplete in lacking punctuation.

Rejections under 35 U.S.C § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The invention appears to employ novel Streptomyces 201. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It does not appears that a deposit was made in this application as filed meeting all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

- 1. Identifies declarant.
- 2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
- 3. States that the deposited material has been accorded a specific (recited) accession number.
- 4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.
- 5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.
- 6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.
- 7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

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Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 and 2 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Bordoloi *et al.*.

Bordoloi *et al.* teach 2-methylheptyl isoniconitate produced by Streptomyces 201. (See, e.g., page 1857.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is 571-272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-9000.

Jew hay Irene Marx Primary Examiner

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